

Proficiency Testing - Time to Enroll for 2003

by Leonard Kargacin

Proficiency testing (PT), as required under Medical Test Site rules 246-338-050, is a source of external quality control. This practice of testing unknown specimens from an outside source provides an additional means to assure quality laboratory testing results. Although labs perform daily internal quality control with their test systems, external quality control provides important interlaboratory comparisons to determine the accuracy and reliability of testing procedures.

Between now and December is the time to enroll to be sure you receive PT samples in 2003. A listing of the currently approved PT programs, their phone numbers, and website addresses can be found on page 3. Call the programs for a free copy of their 2003 PT brochure. If you are enrolled in PT for 2002, your current PT provider will automatically send you a PT order form and catalog for 2003. Remember, if you do not enroll quickly, you will not be guaranteed receipt of samples for the first testing event that occurs between January-March 2003, and will receive 0% for non-participation. This is a failure and may jeopardize your ability to continue testing patient specimens. Be sure to:

- Shop around for prices and test groups.
- Enroll in more than one company, if necessary, to cover all tests.

Information needed to enroll: Complete the 2003 Order Form in the PT brochure with the following information:

- Name (use the name **exactly** as it appears on your MTS license)
- Address
- CLIA ID # (our primary means of identifying your laboratory)

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- MTS license number (see your MTS license)
- Select the appropriate program for your lab (you may have to enroll in several modules and/or companies to cover all analytes).

NOTE: Be sure to indicate on the enrollment form that copies of your PT results must be sent to the Office of Laboratory Quality Assurance; **this must be done for each analyte!**

Regulated analytes:

- Regulated analytes must be covered by modules that ship five samples, three times per year.
- Regulated analytes are listed on the LQA website at www.doh.wa.gov/lqa.htm (Proficiency Testing).
- Don't forget that non-waived tests for Influenza A and B must be covered by PT.
- Some manufacturers of waived tests (e.g. CoaguChek) allow laboratories to choose if they want to perform the test as a waived test following the waived test requirements or as a moderate complexity test following those requirements. If the laboratory chooses to perform the test as a moderate complexity test, it **must** participate in a **five-sample PT program three times per year.**

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	Point-of-Care Testing
ANA	PSA
Bleeding Disorders	Renal Disease
Chlamydia	STD
Diabetes	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Lipid Screening	Wellness

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Non-regulated analytes: All non-waived tests other than the regulated analytes must be tested using one or a combination of the following:

- A two-sample program from one of the proficiency testing providers, or
- Blind samples with known values, or
- Split samples with another lab, or
- Split samples with another instrument or method, or
- 2 analysts perform microscopic test & compare results, or
- Kodachromes of microscopic tests, or
- Correlate patient results with clinical history.

Adding tests during the year:

- Notify our office within 30 days.
- Enroll in PT for regulated analytes before you start testing patient samples.

Deleting tests during the year:

- Notify our office within 30 days.

Temporarily discontinuing tests during the year:

- Notify our office that the test was temporarily discontinued.
- Indicate on PT form that the test was not performed for this event using the code listed in your PT material.
- Notify our office when the test is reinstated.

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Website addresses:

DOH home page: <http://www.doh.wa.gov>

LQA home page: <http://www.doh.wa.gov/lqa.htm>

PHL home page:

<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

Test Categorization Website: The FDA has a new website available for looking up the complexity category (waived, moderate, high) of test systems. The website address is: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>

If you have other questions regarding proficiency testing, contact Leonard Kargacin at (206) 361-2804.

TIPS for Proficiency Testing Success

Improve your chances for successful participation in PT by considering the following suggestions:

- ✓ **Release Results:** Notify PT provider that copies of PT results for **each** analyte are to be sent to the Office of Laboratory Quality Assurance.
- ✓ **Handle PT samples like patient samples:** Don't run them multiple times.
- ✓ **Retain all raw data:** Save data showing the workup of PT samples, instrument printouts, worksheets, log sheets.
- ✓ **Make sure all testing personnel perform PT during the year:** Share or rotate the samples among all staff who perform the test.
- ✓ **Fill in the Method Code:** Do not leave blank.
- ✓ **Correctly report the reason PT was not done:** If you are unable to test for some reason, indicate this on the answer sheet. If you discontinued testing for an analyte, indicate this on the sheet. Immediately notify LQA of any change.
- ✓ **Be timely:** Always be sure to meet the deadline for returning your results.
- ✓ **Review your graded results:** Review your graded PT results with your lab director. Document corrective action for scores below 80%. Evaluate ungraded results.

West Nile Virus

West Nile Virus (WNV) is a flavivirus (a genus of Japanese Encephalitis) commonly found in Africa, West Asia, and the Middle East. It is closely related to St. Louis Encephalitis Virus found in the U.S.

Mosquitoes become infected when they feed on infected birds, such as ravens and crows. After an incubation period of 5 to 15 days, the mosquito can then transmit the virus to humans and animals by biting them. Following this transmission, the virus multiplies in the blood stream. In severe cases, the virus crosses the blood-brain barrier, reaching the brain and causing inflammation of the brain tissue. This inflammation interferes with the central nervous system.

Facts about West Nile Virus:

- WNV is not transmitted from person to person.
- The first appearance of WNV in North America was in 1999.
- There is no evidence that a person can get the WNV from handling live or dead infected birds.
- There is no human vaccine against WNV.

Protecting Yourself:

- Inspect all window and door screens to make sure they are in good condition and free of holes.
- When you are outdoors in areas that have mosquitoes, wear long sleeve shirts and long pants.
- Use mosquito repellent. Repellents greatly reduce your exposure to mosquitoes when applied to exposed clothes and skin.

More information on WNV can be found on the following websites:

Department of Health: www.doh.wa.gov

Northwest Mosquito and Vector Control Association: www.nwmvca.org

Approved Proficiency Testing Providers

Accutest	(800) 356-6788	www.accutest.org/index.html
Amer. Acad. of Family Physicians	(800) 274-7911	www.aafp.org/pt
Amer. Assoc. of Bioanalysts	(800) 234-5315	www.aab.org
American Proficiency Institute	(800) 333-0958	www.api-pt.com
ASIM Medical Lab Evaluation	(800) 338-2746	www.acponline.org/mle/
California Thoracic Society	(714) 730-1944	www.thoracic.org/chapters/state/california/ca.html
College of American Pathologists	(800) 323-4040	www.cap.org
EXCEL (CAP)	(800) 323-4040	www.cap.org
Idaho Bureau of Laboratories	(208) 334-2235	None available at this time
Wisconsin State Lab. of Hygiene	(800) 462-5261	www.slh.wisc.edu/pt/index.html

Still Time to Register!

9th Annual Clinical Laboratory Conference
November 11, 2002
Seattle Marriott Sea-Tac Hotel

Contact Leonard Kargacin at (206) 361-2804 or
leonard.kargacin@doh.wa.gov for registration information.

Waived Testing Helpful Hints

In the last issue, we discussed Good Laboratory Practice (GLP) #1: Have the correct request and collect a good specimen. Here is GLP #2: Label and store specimen properly.

- ✓ Always label the specimen with some type of identifier that is unique to each patient.
- ✓ Add the date and time of collection to the specimen container.
- ✓ If you anticipate a delay in performing the test, store the specimen appropriately. For instance, urine samples for urinalysis may be stored up to 4 hours in the refrigerator. For other specimen storage requirements, refer to the package insert for the test.
- ✓ If the specimen is refrigerated, allow the specimen to come to room temperature before testing.

It is **NOT** good laboratory practice to test specimens that are unlabeled and/or stored improperly!

NOTE: Check this spot in future editions of Elaborations for more helpful hints with waived testing.

Calendar of Events

PHL Training Classes:

Urine Sediments	
November 13	Shoreline
November 14	Shoreline

Parasitology, Part 1 (Helminths)	
December 11 and 12	Shoreline

9th Annual Clinical Laboratory Conference

November 11	Seattle
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WSSCLS/NWSSAMT Spring Meeting

April 24-26, 2003	Pasco
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Northwest Medical Laboratory Symposium

October 22-25, 2003	Olympia
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Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.